UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No. 3176

Total Pages in this Submission 31

TO THE COMMISSIONER FOR PATENTS

Mail Stop Patent Application P.O. Box 1450 Alexandria, VA 22313-1450 ≌ ∪.s. РТО 800277

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

METHOD OF BOTTLE FORMATION AND STORING A PHARMACEUTICAL FORMULATION

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|-------------|---------------------------|-------|------------|-------------------|-------|--------------------|-----------------|--------|---------------------|-----------|------------|
| | vente M·WA | | | THOMAS M. | McC | GRATH | 1 -1 | | | | |
| ∟ If a C | ONT | INU/ | ATION AI | PPLICATION, | , che | eck appropriate L | box and supply | ly the | requisite info | rmation: | |
| | Conti | inual | tion 🗵 | Divisional | | Continuation | -in-part (CIP) |) of | prior applicat | ion No.: | 10/188,486 |
| | h is a Conti h is a | inuat | tion 🗆 | Divisional | | Continuation | -in-part (CIP) |) of | prior applicat | ion No.: | • |
| | Conti | | tion 🗆 | Divisional | | Continuation | -in-part (CIP) |) of | prior applicat | ion No.: | |
| Enclo | sed a | are: | | | | | | | | ****** | |
| | | | | | | Applicatio | n Elements | | | | |
| 1. | X | Filir | ng fee as | calculated an | d tra | ansmitted as des | scribed below | | | | |
| 2. | X. | Spe | cification | having | FIF | FTEEN (15) | _ pages and in | includ | ding the follow | wing: < | |
| | a. | X | Descript | tive Title of the | e Inv | vention | | | | | |
| | b. | X | Cross R | eferences to f | Rela | ated Applications | (if applicable) | ;) | | | |
| | C. | | Stateme | ent Regarding | Fed | derally-sponsored | d Research/De | evelo | pment <i>(if ap</i> | olicable) | |
| | d. | | Referen | ce to Sequen | ce Li | isting, a Table, c | or a Computer | r Prog | gram Listing , | Appendix | |
| | e. | X | Backgro | ound of the Inv | /enti | ion | | | | | |
| | f. | X | Brief Su | ımmary of the | Inve | ention | | | | | |
| | g. | X | Brief De | scription of th | e Dr | rawings (if filed) | - | | | | |
| | h. | X | Detailed | Description | | | | | | | |
| | i. | X | Claim(s) |) as Classified | Bel | low | | | | | |
| | j. | X | Abstract | t of the Disclos | sure | , | | | | | |

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Application Elements (Continued)

| 3. | X | Drawing(s) (when necessary as prescribed by 35 USC 113) | | | | | | | | |
|-----|----|---|--|--|--|--|--|--|--|--|
| | a. | ▼ Formal Number of Sheets TWO (2) | | | | | | | | |
| | b. | ☐ Informal Number of Sheets | | | | | | | | |
| 4. | × | Oath or Declaration | | | | | | | | |
| | a. | ☐ Newly executed (original or copy) ☐ Unexecuted | | | | | | | | |
| | b. | Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional application only) | | | | | | | | |
| | C. | ☑ With Power of Attorney ☐ Without Power of Attorney | | | | | | | | |
| | d. | ☐ <u>DELETION OF INVENTOR(S)</u> Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. 1.63(d)(2) and 1.33(b). | | | | | | | | |
| 5. | X | Incorporation By Reference (usable if Box 4b is checked) The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein. | | | | | | | | |
| 6. | | CD ROM or CD-R in duplicate, large table or Computer Program (Appendix) | | | | | | | | |
| 7. | | Application Data Sheet (See 37 CFR 1.76) | | | | | | | | |
| 8. | | Nucleotide and/or Amino Acid Sequence Submission (if applicable, all must be included) | | | | | | | | |
| | a. | ☐ Computer Readable Form (CRF) | | | | | | | | |
| | b. | ☐ Specification Sequence Listing on: | | | | | | | | |
| | | i. CD-ROM or CD-R (2 copies); or | | | | | | | | |
| | | ii. 🔲 Paper | | | | | | | | |
| | C. | ☐ Statement(s) Verifying Identical Paper and Computer Readable Copy | | | | | | | | |
| | | Accompanying Application Parts | | | | | | | | |
| 9. | | Assignment Papers (cover sheet & document(s)) | | | | | | | | |
| 10. | | 37 CFR 3.73(B) Statement (when there is an assignee) | | | | | | | | |
| 11. | | English Translation Document (if applicable) | | | | | | | | |
| 12. | X | Information Disclosure Statement/PTO-1449 | | | | | | | | |
| 13. | X | Preliminary Amendment | | | | | | | | |
| 14. | X | Return Receipt Postcard (MPEP 503) (Should be specifically itemized) | | | | | | | | |
| 15. | | Certified Copy of Priority Document(s) (if foreign priority is claimed) | | | | | | | | |
| 16. | X | Certificate of Mailing | | | | | | | | |
| | | ☐ First Class ☒ Express Mail (Specify Label No.): EV 108190904 US | | | | | | | | |
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Total Pages in this Submission 31

17. Additional Enclosures (please identify below):

Accompanying Application Parts (Continued)

Request That Application Not Be Published Pursuant To 35 U.S.C. 122(b)(2)

18.

Pursuant to 35 U.S.C. 122(b)(2), Applicant hereby requests that this patent application not be published pursuant to 35 U.S.C. 122(b)(1). Applicant hereby certifies that the invention disclosed in this application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication of applications 18 months after filing of the application.

Warning

An applicant who makes a request not to publish, but who subsequently files in a foreign country or under a multilateral international agreement specified in 35 U.S.C. 122(b)(2)(B)(i), must notify the Director of such filing not later than 45 days after the date of the filing of such foreign or international application. A failure of the applicant to provide such notice within the prescribed period shall result in the application being regarded as abandoned, unless it is shown to the satisfaction of the Director that the delay in submitting the notice was unintentional.

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Total Pages in this Submission 31

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Fee Calculation and Transmittal

| For | #Filed | #Allowed | #Extra | | Rate | Fee |
|---|--------|----------|--------|---|------------------|----------|
| Total Claims | 5 | - 20 = | 0 | x | \$18.00 | \$0.00 |
| Indep. Claims | 2 | - 3 = | 0 | x | \$86.00 | \$0.00 |
| Multiple Dependent Claims (check if applicable) | | | | | | |
| | | _ | | | BASIC FEE | \$770.00 |
| OTHER FEE (specify purpose) | | | | | | |
| | | | 1.7 | | TOTAL FILING FEE | \$770.00 |

A check in the amount of

\$770.00

to cover the filing fee is enclosed.

The Director is hereby authorized to charge and credit Deposit Account No. as described below.

08-0114

acacined below.

☐ Charge the amount of

as filing fee.

Credit any overpayment.

☑ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.

☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Signature

Dated: MARCH 12, 2004

WALTER A. HACKLER, Ph.D. PATENT LAW OFFICE

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CC: